

### **REMARKS**

In the Office Action, claims 1-17 and 19-30 were rejected. By the present response, claims 1, 2, 4, 5, 13, 14, 22, 23 and 25 have been amended, claim 3 has been cancelled and new claim 31 has been added. Upon entry of the amendments, claims 1, 2, 4-17, and 19-31 will be pending in the present patent application. Reconsideration and allowance of all pending claims are requested.

#### **Double Patenting**

In the Office Action, claims 1-10, 13-17, 19 and 22-30 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 14, 16 and 17 of Dumoulin et al., U.S. Patent No. 5,211,165, (hereinafter "Dumoulin '165") in view of Dumoulin et al., U.S. Patent No. 5,251,635, (hereinafter "Dumoulin '635"). Claims 2, 11, 12, 20 and 21 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Dumoulin '165 in view of Dumoulin '635, and further in view of Panescu et al., U.S. Patent No. 5,916,163, (hereinafter "Panescu").

Independent claims 1, 13 and 23 have been amended to more clearly point out certain of the claimed subject matter. Specifically, independent claims 1, 13 and 23 now recite, in generally similar language, *responding in a predetermined fashion when the position of the medical device deviates from the target region of interest*.

Applicants respectfully submit that the double patenting rejection is mooted by the amendments. The amended independent claims 1, 13 and 23 are patentable over Dumoulin '635 and Dumoulin '165 as none of the references either alone or in combination disclose, teach or suggest, and so *cannot claim*, a positioning subsystem that is configured to responding in a predetermined fashion when the position of the medical device deviates from the target region of interest. Claim 3 has been cancelled by the

present response. Claims 2, 4-12, 14-17, 19-22 and 24-30 depend directly or indirectly from claims 1, 13 and 23 respectively. Accordingly, Applicants submit that claims 2, 4-12, 14-17, 19-22 and 24-30 are allowable by virtue of their dependency from an allowable base claim. Applicants also submit that the dependent claims are further allowable by virtue of the subject matter they separately recite. Accordingly, Applicants request that the Examiner reconsider and remove the obviousness-type double patenting rejection of claims 1, 2, 4-17 and 19-30.

### **Rejections Under 35 U.S.C. § 102**

In the Office Action, claims 1-10, 13-17, 19, and 22-30 were rejected under 35 U.S.C. § 102(b) as being anticipated by Dumoulin '635. Anticipation under 35 U.S.C. § 102 requires a showing that each limitation of a claim is found in a single reference, practice or device. *In re Donohue*, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). Applicants respectfully assert that the present invention, as recited in amended independent claims 1, 13 and 23 is patentable over Dumoulin '635.

Independent claims 1, 13 and 23 are amended to more clearly point out certain of the claimed subject matter. Specifically, independent claims 1, 13 and 23 now recite, in generally similar language, *responding in a predetermined fashion when the position of the medical device deviates from the target region of interest*.

The Dumoulin '635 discloses a stereoscopic tracking and imaging system adapted to follow the position and orientation of an invasive device within a subject. In particular, Dumoulin '635 discloses stereoscopic tracking of the three-dimensional position of the invasive device without using X-rays. The Dumoulin '635 also discloses automatic placement and alignment of the subject by use of a support arm within a desired region around invasive device. However, *Dumoulin '635 fails to disclose or suggest positioning of the medical device within the target region of interest without moving the subject*. Applicants respectfully submit that the positioning of the medical

device within the target region of interest may be achieved in the present application either by moving subject or the medical device itself. Specifically, *the present application discloses a positioning subsystem that is configured to respond in a predetermined or pre-programmed fashion when the position of the medical device deviates from the target region of interest. See, Application, page 10, lines 7-12; see also, page 9, lines 12-16.*

The Examiner argued that Dumoulin '635 teaches a monitoring subsystem that is responsive to the movement of the medical device relative to the target region within the subject by activating the imaging system to acquire a new image. The Examiner further argued that the monitoring subsystem disclosed in Dumoulin '635 provides advisory feedback to the interface unit when the medical device deviates from a target position, via a visual icon representing the position of the device. Additionally, the Examiner argued that the feedback provided to the interface can be used to navigate the device to a region of interest.

Applicants respectfully submits that Dumoulin '635 does not disclose or suggest a monitoring and positioning subsystem as recited in the claims. The monitoring subsystem disclosed in Dumoulin '635 is configured only to track the medical device within the subject by repeated acquisition of images. *Dumoulin '635 does not disclose a predetermined or pre-programmed response such as terminating therapy or repositioning the medical device within the target region of interest or activating an advisory message to the interface unit.*

Further, the advisory feedback to the interface unit in the form of visual icon as disclosed in Dumoulin '635 is to provide the position of the medical device within the subject. *Dumoulin '635 does not disclose an advisory feedback such as text or audio that prompts an operator to take a particular course of action during a medical procedure.*

Additionally, Dumoulin '635 discloses automatic placement and alignment of the subject by use of a support arm within a desired region around invasive device based on the feedback. *See*, column 7, lines 24-27. *Dumoulin '635 does not disclose navigating or repositioning the "medical device" during the medical procedure based on the feedback to the interface unit.*

Applicants, therefore, believe that in absence of the positioning subsystem that is configured to respond in a predetermined or pre-programmed fashion as described above, the present invention, as recited in the claims, is not enabled by Dumoulin '635.

At least because Dumoulin '635 fails to disclose or suggest a positioning subsystem that is configured to respond in a predetermined or pre-programmed fashion when the position of the medical device deviates from the target region of interest, as claimed, the reference cannot anticipate claims 1, 13 and 23.

Claim 3 has been cancelled by the present response. Claims 2, 4-10, 14-17, 19, 22 and 24-30 depend directly or indirectly from claims 1, 13 or 23. Accordingly, the Applicants submit that claims 2, 4-10, 14-17, 19, 22 and 24-30 are allowable by virtue of their dependency from allowable base claims. Applicants also submit that the dependent claims are further allowable by virtue of the subject matter they separately recite. Thus, it is respectfully requested that the rejection of claim 1, 2, 4-10, 13-17, 19, and 22-30 under 35 U.S.C. §102(b) be withdrawn.

### **Rejections Under 35 U.S.C. § 103**

In the Office Action, claims 2, 11, 12, 20 and 21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin '635 in view of Panescu. Claims 6, 17, and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin '635 in view of Twiss et al., U.S. Patent No. 5,375,596. Claims 1-10, 13-17, 19, and 22-30 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin '165 in view

of Dumoulin '635. Claims 2, 11, 12, 20 and 21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin '165 in view of Dumoulin '635 and further in view of Panescu.

For the same reasons set forth above, Dumoulin '635 alone or in combination with Dumoulin '165 does not teach, suggest or disclose each and every aspect of Applicants' recited invention as claimed in the independent claims 1, 13 and 23. Claim 3 has been cancelled by the present response. Claims 2, 4-12, 14-17, 19-22, and 24-30 depend directly or indirectly from claims 1, 13 and 23, and are allowable by virtue of such dependency, as well as for the subject matter they separately recite. Thus, it is respectfully requested that the rejection of claims 1, 2, 4-17, 19-30 under 35 U.S.C. §103(a) be withdrawn.

**New claim 31**

Claim 31 depends directly on claim 13 and is therefore allowable by virtue of such dependency, as well as for the subject matter it separately recites.

**Conclusion**

In view of the remarks and amendments set forth above, Applicants respectfully request allowance of the pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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